

Remarks

Introduction

Claims 1-9 were pending. By way of this response, claims 1, 7, and 9 have been amended, and claims 10-20 have been added. Support for the amendments and the new claims can be found in the application as originally filed, and care has been taken to avoid adding new matter. Accordingly, claims 1-20 are currently pending.

Specification Objection

Claim 7 has been objected to for lacking a period at the end of the sentence.

Claim 7 has been amended to include a period, as set forth above. Applicant submits the objection has been overcome and requests that the objection be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Gladstone et al. (2003).

Applicant traverses the rejection as it relates to the present claims.

Gladstone et al. discloses a summary of chronic daily headache, medication overuse headache, chronic migraine, chronic cluster, and other trigeminal autonomic cephalgias and

management of such headache disorders. Importantly, Gladstone et al. distinguishes medication overuse headache from both chronic daily headache and chronic migraine. For example, Gladstone et al. states that medication overuse headache is caused by frequent and excessive use of immediate relief (symptomatic) medications (page 268, right column, first full paragraph). Medication overuse headache is first treated by discontinuing the overused medications (page 269, right column, second full paragraph). Gladstone et al. states that patients "should be provided with symptomatic agents in limited doses ... from drug classes other than those which they [the patients] are overusing to alleviate withdrawal symptoms" (page 270, left column, first full paragraph). After initial detoxification, alternative acute medications to treat breakthrough attacks can be provided in strictly limited doses and prophylactic therapy can be initiated (page 270, bridging sentence).

In contrast to medication overuse headache, Gladstone et al. discloses that chronic daily headache is primarily attributable to benign primary headache disorders (page 266, right column, first full paragraph), and chronic migraine is characterized by headaches fulfilling the criteria for migraine without aura on more than 15 days per month for more than 3 months in the absence of medication overuse (page 271, bridging sentence; emphasis added). Thus, Gladstone et al. specifically discloses that medication overuse headache is distinct and different from both chronic daily headache and chronic migraine, and that the treatment protocols for medication overuse headache is different and distinct from chronic daily headache and chronic migraine.

Gladstone et al. further discloses that botulinum toxin type A (BoNT-A) can be successfully used to treat chronic migraine (which is not a medication overuse disorder) (see Case 3 on page 271). In addition, Gladstone et al. states that BoNT-A is being studied as treatments for migraine and chronic migraine (page 272, right column, third full paragraph).

Applicant disagrees with the Examiner's contention that Gladstone et al. teaches a method of treating patients with medication overuse disorder with botulinum toxin. The Examiner points to pages 271-272 of Gladstone et al. to support her contention. As discussed above, and as discussed at pages 271-272, Gladstone et al. specifically only discloses that botulinum toxin type A can be used to treat chronic migraine. Gladstone et al. does not disclose administration of botulinum toxin to treat medication overuse headache.

Applicant submits that Gladstone et al. does not disclose, teach, or suggest the present invention. For example, Gladstone et al. does not disclose, teach, or even suggest administration of a botulinum toxin to a patient to treat a medication overuse disorder associated with overuse of acute pain medication(s) or to a patient who is overusing acute pain medication(s), as recited in the present claims. In addition, Gladstone et al. does not disclose, teach, or even suggest a treatment method comprising local administration of a botulinum toxin which is effective in reducing the number of headaches and/or the use of the acute pain medication being overused, as recited in certain of the dependent claims.

As discussed above, Gladstone et al. only discloses that botulinum toxin was successfully used to treat chronic migraine in a patient who did not have medication overuse headache (Case 3). In addition, Gladstone et al. discloses that chronic migraine is a condition that is different and distinct from medication overuse disorder, such as medication overuse headache. Furthermore, Gladstone et al. does not disclose, teach, or even suggest that botulinum toxin can be used to treat chronic daily headache.

Applicant acknowledges that Gladstone et al. briefly mentions botulinum toxin as one of many agents which may be used as a prophylactic therapy for medication overuse disorder. However, prophylactic therapies are only employed in patients who have detoxified and stopped using the acute pain medication causing the medication overuse headache. Thus, Gladstone et al. does not disclose, teach, or even suggest administration of a botulinum toxin to a patient who is overusing acute pain medication, or to treat an acute pain medication disorder associated with overuse of acute pain medication, as recited in the present claims.

In view of the above, applicant submits that the present claims, and claims 1-5 and 7-9 in particular, are not anticipated by Gladstone et al. under 35 U.S.C. § 102.

In addition, applicant submits that the present claims are unobvious from and patentable over Gladstone et al. under 35 U.S.C. § 103.

For example, as discussed above, Gladstone teaches that detoxification and prevention of use of the overused medications is the primary treatment goal in treating medication overuse headache. Therefore, Gladstone et al. does not provide any motivation or suggestion to administer an agent such as a botulinum toxin to a patient who is overusing acute pain medication or to treat an acute pain medication overuse disorder associated with overuse of acute pain medication, as recited in the present claims. For example, Gladstone et al. does not disclose, teach, or even suggest local administration (i.e., non-systemic administration) of any pharmaceutical agent to treat medication overuse headache, let alone, local administration of a botulinum toxin to treat medication overuse disorder. In direct contrast, Gladstone et al. discloses that other non-overused symptomatic agents, which are systemically administered, may be used to alleviate withdrawal symptoms associated with the detoxification of the patient (page 270, left column, first full paragraph). Thus, applicant submits that Gladstone et al. actually teaches away from the present claims.

Rejection Under 35 U.S.C. § 103

Claims 1-9 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Katsarava et al. (2003) in view of Aoki (U.S. Patent No. 6,458,365).

Applicant traverses the rejection as it relates to the present claims.

Katsarava et al. discloses a study of relapse rates for patients with medication overuse headache. As stated by Katsarava et al., the treatment of choice for medication overuse headache is complete withdrawal from the overused medication (page 1682, left column, second full paragraph). Katsarava et al. specifically discloses withdrawal from the overused medication as the only treatment protocol for medication overuse headache (page 1682, first paragraph of Methods). Katsarava et al. does not disclose any pharmaceutical treatment of medication overuse headaches, let alone the use of a botulinum toxin to treat medication overuse headaches.

Aoki et al. discloses methods of treating headaches with botulinum toxin. Aoki et al. does not specifically disclose, teach, or suggest the use of botulinum toxin to treat acute pain medication overuse disorders, as recited in the present claims.

Applicant submits that the combination of Katsarava et al. and Aoki et al. does not disclose, teach, or suggest the present invention. For example, the combination of Katsarava et al. and Aoki et al. does not disclose, teach, or even suggest administration of a botulinum toxin to a patient overusing acute pain medication or who has an acute pain medication overuse disorder associated with overuse of acute pain medication, as recited in the present claims.

For example, Katsarava et al. does not disclose any pharmaceutical treatment of medication overuse headache. Applicant submits that Katsarava et al. actually teaches away from the use of pharmaceuticals to treat medication overuse headache, let alone the use of agents such as botulinum toxins

that are locally administered to patients, because Katsarava et al. specifically states that "complete withdrawal from overused medication is the treatment of choice for patients with MOH" (page 1682). Thus, Katsarava et al. does not disclose, teach, or even suggest any pharmaceutical treatment of acute pain medication overuse disorder, let alone such a treatment in a patient who is overusing acute pain medication, as recited in the present claims.

Aoki et al. does not supply the deficiencies apparent in Katsarava et al. For example, Aoki et al. does not specifically disclose, teach, or even suggest administration of a botulinum toxin to treat a patient who is overusing acute pain medication or to treat an acute pain medication overuse disorder associated with overuse of acute pain medication, as recited in the present claims.

Since the combination of Katsarava et al. and Aoki et al. does not disclose, teach, or suggest all of the elements recited in the present claims, applicant submits that the combination of Katsarava et al. and Aoki et al. does not make obvious the present claims.

Furthermore, applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of Katsarava et al. and Aoki et al., let alone to combine the teachings and obtain the present invention. For example, Katsarava et al. teaches away from administration of pharmaceuticals in treating medication overuse headache, as described above. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness."

(*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)).

In view of the above, applicant submits that the present claims, and claims 1-9 in particular, are unobvious from and patentable over Katsarava et al. in view of Aoki et al. under 35 U.S.C. § 103.

In addition, applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.



Conclusion

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-20 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 2/22/05

Respectfully submitted,

  
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